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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 09/938,885 | Applicant(s) BANDMAN ET AL. | |
| | Examiner David S Romeo | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-15,17,20,25,26,43 and 45 is/are pending in the application.
- 4a) Of the above claim(s) 3-5,7-13,17,20,25,26,43 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5,7-15,17,20,25,26,43 and 45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>0801</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 10/29/2003 has been entered. Claims 1-5, 7-15, 17, 20, 25, 26, 43, 45 are pending.

5 Applicant's election with traverse of group 1 (claims 1, 2, 14, 15) in the paper filed 10/29/2003 is acknowledged. The traversal is on the ground(s):

that groups I, II, and III could be examined without undue search burden;

that groups VI and VII should be examined with group I;

that groups IV and V should be examined with group II; and,

10 that groups I and II could be examined without undue burden;

This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed invention if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05(i)). The groups are distinct for the reasons given in the Office action
15 mailed 09/29/2003. Furthermore, separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a prima facie case that the search and examination of the plural inventions imposes a serious burden upon the Examiner. See M.P.E.P. § 803. Such separate classification is set forth in the Office action mailed 09/29/2003. Polynucleotide and polypeptide searches are not coextensive as indicated by
20 their separate classification. Applicant has offered no evidence to rebut this showing.

Contrary to Applicants' assertion that any search of the prior art in regard to group I will reveal whether any prior art exists as to the other groups, a search is directed to references which would render the invention obvious, as well as references directed to

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anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. In accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), process claims 17 and 20, which do not depend from or otherwise include all the limitations of the allowable product, will NOT be rejoined.

5 The requirement is still deemed proper and is therefore made FINAL.

 Claims 3-5, 7-13, 17, 20, 25, 26, 43, 45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 10/29/2003.

 Claims 1, 2, 14, 15 are being examined.

Claim Rejections - 35 USC § 102

15 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

20 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

 Claims 1, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Noguchi

(A). Noguchi discloses a pentapeptide having the primary structure Asp-Ser-Asp-Gly-Lys (column 2, lines 40-45). By high performance liquid chromatography the purity of the peptide was 97% (column 6, lines 45-50). 97% purity is indistinguishable from the term “isolated” in the present claims. The amino acid sequence Asp-Ser-Asp-Gly-Lys is

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Db 70 KEKFGKPNKRKGFSEGLWEIENNPTVKASGYQSSQKKSCVEEPEPEPEAAEGDGDKKGNA 129
 QY 125 EGSSDEEGKLVIDEPAKEKNEKGALKRRAGDLEDSPKRPKEAENPEGEEKEAATLEVER 184
 Db 130 EGSSDEEGKLVIDEPAKEKNEKGALKRRAGDLEDSPKRPKEAENPEGEEKEAATLEVER 189
 QY 185 PLPMEVEKNSTPSEPGSGRGPXXXXXXXEEATKEDAEAPGIKSHESL 235
 Db 190 PLPMEVEKNSTPSEPGSGRGPQEEEEEEDEEEATKEDAEAPGIRDHESL 240.

Nakamura also discloses the expression of HDGF by Cos-7 cells transfected with its cDNA. The HDGF was adsorbed to a heparin Sepharose column and eluted. Page 25146, right column, full paragraph 2. The eluted HDGF is indistinguishable from the term “isolated polypeptide” in the present claims. The eluted HDGF comprises an amino acid sequence “at least 90% identical to an amino acid sequence of SEQ ID NO:1,” as indicated above. Nakamura indicates that samples were dialyzed against PBS prior to assaying (page 25144, left column, full paragraph 1; Table I; Figure 4). PBS is a “pharmaceutically acceptable excipient,” as evidenced by Cummins (column 12, full paragraph 2).

Alternatively, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to dialyze the purified or eluted HDGF samples against PBS prior to assaying, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification in order to eliminate PBS as variable in the samples tested in the assay. Note that PBS is the control in both Figure 4 and Table I. PBS is a “pharmaceutically acceptable excipient,” as evidenced by Cummins (column 12, full paragraph 2). The invention is prima facie obvious over the prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10

Claims 1, 2, 14, 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

15

The claims are directed to or encompass a polypeptide comprising an amino acid sequence of SEQ ID NO: 1. SEQ ID NO: 1 comprises the sequence "Xaa-Xaa-Xaa-Xaa-Xaa-Xaa-Xaa-Xaa-Xaa-Xaa." Clearly, if one were to make SEQ ID NO: 1, one would have to insert amino acid residues at each of these ten positions. There are no functional limitations to the genus of polypeptides to which the claims are directed or encompass. The present specification does not provide a specific assay to determine which of the embodiments has the desired activity. Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (U) page 1306, column 1, full paragraph 1, or Ngo (V) page 433, full paragraph 1, and page 492, full paragraph 2.

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The claims are directed to or encompass “a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to an amino acid sequence of SEQ ID NO: 1.” The specification provides no guidance that would allow those skilled in the art to determine, with a reasonable degree of confidence, whether any of the sequences that are at least 90% identical to SEQ ID NO: 1 occur naturally and, if so, which they would be. The only way to definitely determine the scope of the claims would be to compare SEQ ID NO: 1 to all naturally occurring sequences, which is clearly an impossible task. In addition, there are no functional limitations to the genus of polypeptides to which the claims are directed or encompass. The present specification does not provide a specific assay to determine which of the embodiments has the desired activity. Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (U) page 1306, column 1, full paragraph 1, or Ngo (V) page 433, full paragraph 1, and page 492, full paragraph 2.

Applicant is advised that while a specification need not disclose what is well known in the art, that rule does not excuse an applicant from providing a complete disclosure. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

The skilled artisan is left to an extensive amount of experimentation, wherein encompassed polypeptides are randomly made and through trial and error experimentation is left to determine how to use such polypeptides.

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The claims are extremely broad because claims 1 and 14 encompass polypeptides “comprising a naturally occurring amino acid sequence at least 90% identical to an amino acid sequence of SEQ ID NO: 1.” On its face, claims 1 and 14 appear to encompass any polypeptide that is at least 90% identical to SEQ ID NO: 1 and that occurs in nature.

- 5 This claim scope would appear to encompass alleles of LGFV (i.e., LGFVs that occur naturally within the human population); homologous LGFV polypeptides from other species, provided they are at least 90% identical to LGFV; and other polypeptides (e.g., other polypeptides, from any species) that are at least 90% identical to LGFV. The scope of the present claims does not bear a reasonable correlation to scope of enablement
- 10 provided by the present specification because the specification only provides a single polypeptide defined by the amino acid sequence of SEQ ID NO: 1. There is not a single example in the instant specification, working or prophetic, of an "LGFV" protein whose amino acid sequence deviates from SEQ ID NO: 1. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of
- 15 work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues in the amino acid sequence of SEQ ID NO: 1 which are required for the functional and structural integrity of that protein. It is this additional characterization of that single disclosed, naturally occurring protein that is required in order to obtain the
- 20 functional and structural data needed to permit one to practice the full scope of the claimed invention. It is this additional characterization that constitutes undue experimentation.

Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not without actually making and testing them then the instant application does not support the breadth of the claims. In the instant case it is highly improbable that any protein having 90% amino acid sequence identity to the disclosed protein will more likely than not perform in the manner disclosed and the instant specification does not provide the guidance needed to predictably alter that sequence with any reasonable expectation that the resulting protein will function as an "LGFV."

In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claims 1, 2, 14, 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to or encompass a polypeptide comprising an amino acid sequence of SEQ ID NO: 1. SEQ ID NO: 1 comprises the sequence "Xaa-Xaa-Xaa-Xaa-

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Xaa-Xaa-Xaa-Xaa-Xaa-Xaa.” Clearly, if one were to make SEQ ID NO: 1, one would have to insert amino acid residues at each of these ten positions. The claims are directed to or encompass “a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to an amino acid sequence of SEQ ID NO: 1.” There are no

5 functional limitations to the genus of polypeptides to which the claims are directed or encompass.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial

10 structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure. There is no identification of any particular function that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying
15 characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written
20 description' inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of

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polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is

5 required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification
10 provided only the bovine sequence.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1, 2, 14, 15 are rejected under 35 U.S.C. 112, second paragraph, as being
15 indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 2, 14, 15 are indefinite over the recitation of "an amino acid sequence of SEQ ID NO: 1" because it is unclear if the entire amino acid sequence of SEQ ID NO: 1 or some portion of the amino acid sequence of SEQ ID NO: 1 is intended. The metes and bounds are not clearly set forth.

20

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite over the recitation of "biologically active

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fragment” because it is unclear what biological activity is intended. The metes and bounds are not clearly set forth.

Claims 1, 2, 14, 15 are rejected under 35 U.S.C. 112, second paragraph, as being
5 indefinite for failing to particularly point out and distinctly claim the subject matter
which applicant regards as the invention. The specification intends that the term "amino
acid sequence" and like terms, such as "polypeptide" or "protein" are not meant to limit
the amino acid sequence to the complete, native amino acid sequence associated with the
recited protein molecule (page 4). The specification also discusses LGFV variants,
10 deletions, insertions, substitutions, and additions (page 5). It is unclear if the present
claims (claims 1, 2, 14, 15) encompass those embodiments or if the claims only
encompass the entire, specific, unaltered amino acid sequences that are recited without
substitutions, insertions, additions, or deletions (although the open claim language
permits additional sequences before and/or after the recited sequence). The metes and
15 bounds are not clearly set forth.

Claims 1, 14 are rejected under 35 U.S.C. 112, second paragraph, as being
indefinite for failing to particularly point out and distinctly claim the subject matter
which applicant regards as the invention. Claims 1 and 14 encompass polypeptides
20 “comprising a naturally occurring amino acid sequence at least 90% identical to an amino
acid sequence of SEQ ID NO: 1.” On its face, claims 1 and 14 appear to encompass any
polypeptide that is at least 90% identical to SEQ ID NO: 1 and that occurs in nature.
This claim scope would appear to encompass alleles of LGFV (i.e., LGFVs that occur

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naturally within the human population); homologous LGFV polypeptides from other species, provided they are at least 90% identical to LGFV; and other polypeptides (e.g., other polypeptides, from any species) that are at least 90% identical to LGFV.

If this claim construction were accurate, the claims would be extremely broad,
5 although that by itself does not make it indefinite.

When the claims are read in light of the specification, however, the intended scope of the claim becomes unclear. A review of the specification shows that there is no disclosure of the literal language of the claims. Of course, the test for definiteness is not literal support but whether one skilled in the art would understand the bounds of the
10 claim when read in light of the specification.

The following passages from the specification seem to be the most relevant for construing the claim:

- 15 • The invention also encompasses LGFV variants. A preferred LGFV variant is one having at least 90% amino acid sequence similarity to the LGFV amino acid sequence (SEQ ID NO:1)."
Paragraph bridging pages 11-12. 'A "variant" of LGFV, as used herein, refers to an amino acid sequence that is altered by one or more amino acids.' Page 5, lines 12-13.
- 20 • Altered nucleic acid sequences encoding LGFV which are encompassed by the invention include deletions, insertions, or substitutions of different nucleotides resulting in a polynucleotide that encodes the same or a
25 functionally equivalent LGFV. The encoded protein may also contain deletions, insertions, or substitutions of amino acid residues which produce a silent change and result in a functionally equivalent LGFV. Deliberate amino acid substitutions may be made on the basis of
30 similarity in polarity, charge, solubility, hydrophobicity, hydrophilicity, and/or the amphipathic nature of the residues as long as the biological activity of LGFV is retained. Page 13, lines 8-12.
- 35 • Also included within the scope of the present invention are alleles of the genes encoding LGFV. As used herein, an "allele" or "allelic sequence" is an alternative form of the gene which may result from at least one mutation in the nucleic acid sequence. Alleles may result in

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altered mRNAs or polypeptides whose structure or function may or may not be altered. Any given gene may have none, one, or many allelic forms. Common mutational changes which give rise to alleles are generally ascribed to natural deletions, additions, or substitutions of nucleotides. Each of these types of changes may occur alone, or in combination with the others, one or more times in a given sequence. Page 13, lines 20-27

The specification provides no guidance that would allow those skilled in the art to determine, with a reasonable degree of confidence, whether any of the sequences that are at least 90% identical to SEQ ID NO: 1 occur naturally and, if so, which they would be. The only way to definitely fix the scope of the claims would be to compare SEQ ID NO: 1 to all naturally occurring sequences, which is clearly an impossible task. Thus, the metes and bounds of the claim are unclear.

Since the scope of the claims cannot be determined, the claims are indefinite.

Information Disclosure Statement

The information disclosure statement filed 08/24/2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication. The publications lined through on the IDS do not provide a date of publication. It has been placed in the application file, but the information referred to therein that has been lined through has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement,

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including all certification requirements for statements under 37 CFR 1.97(e). See MPEP

§ 609 ¶ C(1).

Conclusion

5 No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (571) 272-0887.

10 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

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15 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

20


25 DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
FEBRUARY 11, 2004